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10/731,459

12/09/2003

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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

PAPER NUMBER

1743

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/731,459

Applicant(s)

WIEN ET AL.

Examiner

Bobby Ramdhanie, Ph.D.

Art Unit

1709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/09/2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION***Information Disclosure Statement***

1. The information disclosure statement filed 12/09/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The information disclosure statement lists "Other Art" which has not been submitted. As a result, this document has not been considered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 1-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51 & 66-117 of copending Application No. 10/731230. Claims 1-39 of the instant application recite a sensor and a method of using the sensor. Claims 1-51 & 66-117 of Application No. 10/731230 recite a sensor and a method of using the sensor. Examiner takes the position that the sensor and the method of using the sensor of the instant application and the test strip and the method of using the test strip of Application No. 10/731230 define obvious variants of one another.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 9, 18, 21, 24, 25, 27, & 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Masuda (US4414323). Regarding Claim 1, Masuda teaches a sensor of Claim 1 comprising a support (Abstract), a sampling layer which can react with a target species to form or release a signal compound which is capable of effecting a reaction with silver halide to form a latent image (Abstract), and a signal amplification layer comprising silver halide (Column 3 line 66 – Column 4 line 8). Examiner takes the position that the silver image is equivalent to the latent image.

3. For Claim 3, Masuda teaches a sensor of Claim 1, wherein the signal compound can react with a secondary compound (Column 4 line 13) contained in the silver halide layer which can then react with silver halide to form a latent image (Column 4 lines 8-30).
4. For Claim 9, Masuda teaches the sensor of Claim 1, wherein the silver halide layer contains a dye image forming coupler (Column 15 lines 44-52).
5. For Claim 18, Masuda teaches the sensor of Claim 1, wherein the silver halide is sensitized (Column 13 lines 46-57).
6. For Claim 21, Masuda teaches all of the claim limitations of Claim 1. Masuda further teaches the sensor of Claim 1 wherein the signal compound (dye coupler) is capable of effecting a reaction with the silver halide by reacting with the light-blocking layer to effect a reaction with silver halide to form a latent image (Column 15 lines 44-61). Examiner takes the position that the silver emulsion layer may act as a light-blocking layer.
7. For Claim 24, Masuda teaches the sensor of Claim 1 wherein the sensor can detect more than one type of contaminant (Column 3 lines 4-12).
8. For Claim 25, Masuda teaches the sensor of Claim 1 wherein the target species is *E. Coli*. (Column 3 lines 4-12). Examiner takes the position that bacteria are equivalent to *E. Coli*.
9. For Claim 27, Masuda teaches the sensor of Claim 1 further comprising a filter layer (Column 14 lines 51-54).

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10. For Claim 28, Masuda teaches the sensor of Claim 1 wherein the sampling layer is above the signal amplification layer (Abstract). Examiner takes the position that structure A is the sampling layer and structure B is the signal amplification layer.

11. Claims 1, 4, 29, & 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Masuda et al (US5300421). Regarding Claim 1, Masuda et al teaches a sensor of Claim 1 comprising a support (Abstract), a sampling layer which can react with a target species to form or release a signal compound which is capable of effecting a reaction with silver halide to form a latent image (Abstract), and a signal amplification layer comprising silver halide (Column 31 lines 33-37). Examiner takes the position that the silver image is equivalent to the latent image.

12. For Claim 4, Masuda et al teaches the sensor of Claim 1, wherein the signal compound can react with silver halide to form a latent image (Column 5 lines 5-10).

13. For Claim 29, Masuda et al teaches the sensor of Claim 1, wherein the silver halide amplification layer comprises A). Silver halide that upon LIFCS exposure provides a latent image in exposed grains that are capable of acting as a catalyst for the subsequent formation of a silver image in a development step (Column 2 line 65 to Column 3 line 13); B) a non-LIFCS sensitive source of reducible silver ions (Column 32 line 49); C) A reducing composition for the reducible silver ions (Column 7 lines 4-62), and D) a hydrophilic or hydrophobic binder (Column 33 lines 17-43 and Column 34 lines 24-33). Examiner takes the position that colloidal silver is a type of insensitive grain as taught by Abe (Abstract; US5631123).

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14. For Claim 30, Masuda et al teaches a method of detecting a contaminant comprising contacting the sensor of Claim 1 with the material to be tested and allowing the silver halide to form a latent image (Column 4 line 56 to Column 5 line 67).

15. For Claim 31, Masuda et al teaches the method of Claim 30 further comprising the step of developing the latent image to form a detectable signal (Column 35 line 4-Column 36 line 6).

16. For Claim 32, Masuda et al teaches the method of Claim 30 wherein the detectable signal is measurable (Column 35 line 4 – Column 36 line 6).

17. For Claim 33, Masuda et al teaches the method of Claim 30, wherein the latent image is developed by heat (Column 43 lines 30-33).

18. For Claim 34, Masuda et al teaches the method of Claim 30, wherein the latent image is developed by chemical processing (Column 43 line 30-36).

19. For Claim 35, Masuda et al teaches the method of Claim 30 further comprising reading the signal (Column 35 line 4 – Column 36 line 6). Examiner takes the position that use of the densitometer allows the signal to be read.

20. For Claim 36, Masuda et al teaches the method of Claim 35, where the signal is read visually (Column 35 line 4 – Column 36 line 6). Examiner takes the position that use of the densitometer allows the signal to be read.

21. For Claim 37, Masuda et al teaches the method of Claim 35, wherein the signal is read by a densitometer (Column 35 line 4 – Column 36 line 6).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 2, 5, 6-8, 10-15, 19, & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda in view of Figueras (US4144306). Regarding Claim 2, Masuda teaches a sensor of Claim 1. Masuda does not teach the sensor of Claim 1, wherein the sensor further comprises an additional layer which blocks electromagnetic radiation which is capable of exposing silver halide. Figueras teaches this feature. Figueras teaches a sensor wherein the sensor comprises an additional layer which blocks electromagnetic radiation that is capable of exposing silver halide (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because this would prevent premature exposure of the silver halide and generation of false positive results.

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25. For Claim 5, Masuda teaches the sensor of Claim 1. Masuda does not teach the sensor of Claim 1 wherein the support is opaque. Figueras teaches this feature. Figueras teaches that the support may be opaque (Column 8 lines 11-19). It would have been obvious to one of ordinary skill at the time the invention was made to modify Masuda to use a support, which is opaque for contrast quality and enhanced resolution of developed images.

26. For Claim 6, Masuda in combination with Figueras, teach the sensor of Claim 2. Masuda does not teach that the sensor of Claim 2 wherein said light-blocking layer is positioned between the sampling layer and the silver halide layer. Figueras teaches this feature. Figueras teaches the use of a light-blocking layer that is positioned between the sampling layer and the silver halide layer (Abstract 2nd Paragraph). It would have been obvious to one of ordinary skill at the time the invention was made to modify Masuda with Figueras because according to Figueras, this layering would allow for enhanced detection of the preformed detectable moiety by reflection densitometry or other appropriate radiometric techniques (Abstract 2nd Paragraph).

27. For Claim 7, Masuda teaches the sensor of Claim 1. Masuda does not teach the sensor of Claim 1, wherein the sampling layer also blocks electromagnetic radiation, which is capable of exposing the silver halide. Figueras teaches this feature. Figueras teaches the sensor of Claim 1 wherein the sampling layer also blocks electromagnetic radiation, which is capable of exposing the silver halide (column 23 lines 39-53). Examiner takes the position that the coatings and the fibers, which make up the reagent layer can act to block radiation. It would have been obvious to one of ordinary skill in he

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art at the time the invention was made to modify Masuda with Figueras because according to Figueras these types of impregnation are well-known techniques (Column 23 lines 51-53).

28. For Claim 8, Masuda teaches the sensor of Claim 2. Masuda does not teach the sensor of Claim 2, wherein the sampling layer is located between the light blocking layer and the silver halide layer. Figueras teaches this feature. Figueras teaches the sensor of Claim 2 wherein the sampling layer is located above light blocking layer and the silver halide layer(Figures 2 & 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda in view of Figueras to have the sampling layer between the radiation-blocking layer and the silver halide layer because this would reduce the occurrences of false readings from radiation activating the silver halide layer.

29. For Claim 10, Masuda in combination with Figueras teach all of the claim limitations of Claim 2. Figueras further teaches that the radiation-blocking sensor is diffusible (Abstract 2nd Paragraph). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because this would allow the signal compound to continue through the sensor and interact with the silver halide.

30. For Claim 11, Masuda in combination with Figueras teaches the sensor of Claim 6. Figueras further teaches the light-blocking layer is diffusible to the signal compound (Abstract 2nd Paragraph and Claim 12). Examiner takes the position that a signal compound and a diffusible product are equivalent). It would have been obvious to one

of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because this would allow the signal compound to interact with the silver halide and produce a latent image.

31. For Claim 12 Masuda in combination with Figueras teach all of the claim limitations of Claim 8. Figueras further teaches the light-blocking layer is diffusible to the target species (Claim 7 & 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because this would allow a comparison with the target species and its reactivity with a variety of substances, which may produce a signal compound.

32. For Claim 13, Masuda in combination with Figueras teach all of the claim limitations of Claim 2. Figueras further teaches that the light-blocking layer is opaque (Abstract 2nd Paragraph). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Masuda with Figueras because according to Figueras, this would enhance the detection of the preformed detectable moiety in the silver halide layer or in the sampling layers by reflection densitometry or other appropriate radiometric technique (Abstract 2nd Paragraph).

33. For Claim 14, Masuda in combination with Figueras teach all of the claim limitations of Claim 2. Figueras further teaches that the light-blocking layer contains a pigment (Column 20 lines 64-67). Examiner takes the position that colorant is the equivalent as pigment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because according to

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Figueras, these opacifying agents provide a radiation inhibiting effect (Column 20 lines 61-67).

34. For Claim 15, Masuda in combination with Figueras teaches all of the claim limitations of Claim 14. Examiner takes the position that colorant is the equivalent as pigment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because according to Figueras, these opacifying agents provide a radiation inhibiting effect (Column 20 lines 61-67).

35. For Claim 16, Masuda in combination with Figueras teach all of the claim limitations of Claim 14. Figueras further teaches that the definition of a colorant is a dye (Column 11 line 48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because according to Figueras, these opacifying agents provide a radiation inhibiting effect (Column 20 lines 61-67).

36. For Claim 19, Masuda teaches all of the claim limitations of Claim 1. Masuda does not teach that the signal compound is capable of effecting a reaction through a chemical cascade. Figueras teaches this feature. Figueras teaches that the signal compound is capable of effecting a reaction through a chemical cascade (Column 16 line 55 to Column 18 line 67). Examiner takes the position that the signal compound is the preformed detectable moiety found in the reagent layer. The analyte is used both directly and indirectly in the chemical cascade via dye couplers. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

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Masuda with Figueras because according to Figueras these release type mechanisms are widely known (Column 16 lines 61-65).

37. For Claim 20, Masuda teaches all of the claim limitations of Claim 1. Masuda does not teach the signal compound is formed through a chemical cascade. Figueras teaches this feature (Column 11 lines 56-67). The analyte is used both directly and indirectly in the chemical cascade via dye couplers. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because according to Figueras these release type mechanisms are widely known (Column 16 lines 61-65).

38. For Claim 23, Masuda et al teaches the all of the claim limitations of Claim 1. Masuda et al does not teach a removable protective layer over the sampling layer. Figueras teaches this feature (Figure 4 & Column 8 lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda with Figueras because according to Figueras, this would allow for better optical transmission and detection of radiometrically detectable species (Column 8 lines 8-19).

39. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al, Figueras and in further view of Dostes et al (US3237008). Regarding Claim 17, Masuda et al in combination with Figueras, teach all the claim limitations of Claim 2. Masuda et al in Figueras do not teach that the light-blocking layer contains non-light sensitive silver. Dostes et al teaches this feature (Figure 2 and Column 2 lines 9 –34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda et al and Figueras with Dostes et al because this would allow

one to handle a photographic element for x-rays under ordinary room-light illumination (Column 1 lines 65-69).

40. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Kimura et al (US6140102). Regarding Claim 22, Masuda et al teaches all of the claim limitations of Claim 1. Masuda et al does not teach that the sampling layer and signal amplification layer comprising silver halide are the same layer. Kimura et al teaches this feature (Column 10 lines 18-28). It would have been obvious to one of ordinary skill in the art because according to Kimura et al, this would be an example of a high-speed type X-ray film (Column 10 lines 26-28).

41. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Tan et al (US6140102). Regarding Claim 26, Masuda et al teaches the sensor of Claim 1. Masuda et al does not teach that the signal compound is methanethiol. Tan et al teaches this feature (Column 7 line 61 to Column 8 line 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Masuda et al with Tan et al because Masuda et al teaches the element may be used to detect bacteria and that Tan et al teaches one way of detecting the presence of bacteria by obtaining a signal compound, methanethiol.

42. Claims 38 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Sakanoue et al (US4500634). Regarding Claim 38, Masuda et al teaches all of the claim limitations of Claim 35. Masuda does not teach that the signal is electronically scanned. Sakanoue et al teaches this feature (Column 5 lines 25-55). It would have been obvious to one of ordinary skill in the art at the time the invention was

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made to electronically scan the signal because this would eliminate the human objectivity in determining the visual sharpness of the signal being scanned.

43. For Claim 39, Masuda et al in combination with Sakanoue et al teach all of the claim limitations of Claim 38. Sakanoue et al further teaches the results of the electronic scan are analyzed using a computer (Column 5 lines 25-55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to electronically scan the signal because this would eliminate the human objectivity in determining the visual sharpness of the signal being scanned.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-272-1447. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-270-3240. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR


WALTER D. GRIFFIN
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